REMARKS

The undersigned attorney for Applicants thanks Examiner Di Nola Baron for extending the courtesy of a telephone interview on June 12, 2003. During the interview, the Examiner agreed that the claims as amended herein distinguish over Bell, and the Examiner stated that the amendment was likely to be entered.

Claim 1 is amended to make it clear that the mesh reinforcing component is integrated with the foam component and that the pores of the foam penetrate and are integrated with the mesh. This amendment is made to expedite the prosecution of the application and Applicants submit that the claim scope is not changed and that the claim amendments are not made for purposes related to patentability. No new matter is added by these amendments.

The outstanding Office Action addresses and rejects claims 1-17. Applicants respectfully request reconsideration of the present application in view of the following remarks.

35 U.S.C. §103(a) Claim Rejections

Rejection Pursuant to Bell et al.

The Examiner rejects claims 1-17 pursuant to 35 U.S.C. 103(a), alleging that the claims are obvious over U.S. Patent No. 6,179,872 to Bell et al. (Bell).

In particular, the Examiner argues that Bell discloses a biopolymer matt that comprises various layers of biopolymer foams and that the porosity of the matt can be manipulated by various physical or chemical methods. The Examiner further states that Bell teaches that the foam layer has low density and high porosity and the matt composition can incorporate fiber structures to achieve general reinforcement, and, specifically, biopolymers can be used to create matts, which can be supported by polymer mesh. In regard to the claimed mesh density, the Examiner argues that one would have been able to determine the optimal mesh density by routine experimentation.

The Examiner's position is further clarified by comments in response to Applicants' previous response, which appear on page 4 of the Office Action. There the Examiner states:

> Applicant argues that Bell et al. fails to teach that the pores of the foam component penetrate and interlock with the mesh of the reinforcing component having 12-80% mesh density. In response tosaid arguments, it is noted that Bell et al. provides the general teachings that the matt composition can incorporate fiber structures to achieve general reinforcement (See col. 3, lines 10-56), and, specifically, biopolymers can be used to create matts, which can be supported by polymer mesh (See col. 5, lines 56-64). Bell et al. teaches that the biopolymer foams can be bonded to a polymer mesh (See col. 8, lines 60-64) and the strength of the matt can be increased by laying reinforcing material into the fibrils, including biopolymer fabrics of a selected size and density (See col. 11, lines36-62). Thus Bell et al. teaches that the reinforcing material can penetrate into the fibrils and the mesh density can be selected to be in the desired range.

Applicants respectfully traverse this rejection.

The claimed invention is directed to a biocompatible tissue repair stimulating implant, that includes a bioabsorbable polymeric foam component having pores with an open cell pore structure. The reinforcing component is formed of a biocompatible, mesh-containing material having a mesh density in the range of about 12 to 80%. In another aspect of the invention, the foam component is integrated with the reinforcing component such that the pores of the foam component penetrate the mesh of the reinforcing component and interlock with the reinforcing component. The implant also includes at least one biological component in association with the implant.

Applicants have discovered that allowing the foam component to bond through and interlock with the mesh reinforcing component greatly improves the strength of the implant. The interlocking nature of the pores of the foam with the mesh is an important feature of the claimed invention that contributes to enhanced properties. Further, this interlocking of the pores with the mesh is made possible by the mesh having a mesh density, or measure of mesh open space, in the claimed range. Applicants have found that an interlocking structure is not possible without a mesh density in the claimed range.

Bell entirely fails to disclose or suggest any such tissue repair stimulating implant, as well as any implant having the claimed mesh density. In fact, Bell makes only a limited reference to a mesh material, stating that it can be used as a *support for Bell's matt*. There is no mention whatsoever in the Bell disclosure teaching or suggesting that a foam component of a biocompatible implant can be integrated with a mesh reinforcing component so that the pores of the foam penetrate and interlock with the mesh.

The Examiner's rejection seems to be based on her reasoning that

> biopolymers can be used to create matts, which can be supported by polymer mesh (See col. 5, lines 56-64). Bell et al. teaches that the biopolymer foams can be bonded to a polymer mesh (See col. 8, lines 60-64) and the strength of the matt can be increased by laying reinforcing material into the fibrils, including biopolymer fabrics of a selected size and density (See col. 11, lines 36-62). Thus Bell et al. teaches that the reinforcing material can penetrate into the fibrils and the mesh density can be selected to be in the desired range.

Office Action, p. 4.

This reasoning, and the eventual conclusion that Bell renders obvious the claimed invention, is not factually supported. The Examiner admits that Bell merely teaches that Bell's foams are *bonded* to mesh. A foam that is *bonded* to mesh is not one that is integrated with the mesh such that pores of the foam penetrate the mesh and interlock with the reinforcing component. There is simply no support in Bell for the Examiner's statement that Bell "teaches that the reinforcing material can penetrate into the fibrils and the mesh density can be selected to be in the desired range." The only discussion of such a structure and property of an implant material appears in Applicants' disclosure.

The fact that Bell only teaches the *bonding* of foams to mesh actually teaches away from the claimed invention. When foams that are simply bonded to mesh, there is no need to have the claimed mesh density, since the pores of the foam do not need to penetrate the mesh. In fact, any such property or structure might actually inhibit the bonding of the foam and mesh.

The Examiner's reference to the possibility that Bell's matt can be constructed of and reinforced with fibrils, is not relevant to the pending claims. The fibrils and other reinforcing

materials disclosed by Bell are not mesh. Mesh is distinguished from the reinforcing materials in the Bell reference, and mesh is only disclosed as being useful to be *bonded* to a matt to *support* a matt. The presence of non-mesh reinforcing materials fails to support the Examiner's rejection because these materials are not mesh and they cannot and do not have the density properties that are claimed and that are necessary to enable the pores to penetrate and interlock wth the mesh.

At best, Bell discloses only the use of similar materials (foam and mesh) used in a bioimplant. However, Bell's disclosure of such similar materials is not sufficient to render obvious the claimed invention. Bell's failure to provide any teaching or suggestion that the pores of the foam component could penetrate and interlock with the mesh of the reinforcing component precludes the use of this reference in a rejection of the pending claims pursuant to Sections 102 or 103.

For the foregoing reasons Applicants submit that the pending claims distinguish over the cited reference and respectfully request allowance thereof.

The Examiner is urged to telephone the undersigned Attorney for Applicants in the event that such communication is deemed to expedite allowance of this application.

Respectfully submitted,

NUTTER, MCCLENNEN & FISH, LLP

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William C. Geary III
Reg. No. 31,359
Attorney for Applicant(s)

155 Seaport Blvd.
World Trade Center West
Boston, MA 02210-2699
Tel: (617) 439-2766
Fax: (617) 310-9766